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March 14, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
United States Food and Drug Administration
Office of the Commissioner
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: The Medical Device User Fee Modernization Act of 2002 – Docket No. 02N-05341

Dear Dr. von Eschenbach:

I am writing on behalf of America's Health Insurance Plans (AHIP) representing 1,300 member companies providing health insurance coverage to more than 200 million Americans to provide comments on the Medical Device User Fee Modernization Act and to follow-up on previous discussions with your staff about collaborative initiatives to improve the safety and efficacy of pharmaceutical products and medical devices.

Our comments are designed to urge you to consider analyzing the long-term safety and effectiveness of prescription drugs, biological products, and medical devices as part of FDA's enforcement activity and to set aside funding for ongoing effectiveness analysis and comparisons across available treatments. We believe the agency has an important role to play in facilitating the transition to a more evidence-based, safe, and effective health care system and we are making five recommendations to help achieve these goals.

1. Require and Adequately Fund Post-Market Studies of Prescription Drugs, Biological Products, and Medical Devices

The FDA has committed significant resources to pre-market testing of prescription drugs, biological products, and medical devices through funding available under the Prescription Drug User Fee Act and the Medical Device User Fee Act. As the population ages and the number of individuals with multiple chronic diseases increases, it is critical that FDA expand its activities to include post-marketing surveillance that focuses on the long-term effects of drugs, biologics, and devices.

We believe that FDA should require manufacturers to conduct selected post-market studies of their products, including situations where safety concerns have not been raised, to determine if the drug, biologic, or device is safe, effective, and fulfilling its intended purpose. In addition, FDA should seek adequate support for its post-market surveillance activities through user fee funding. The Prescription Drug User Fee Act and the Medical Device User Fee Act provide critical resources to conduct cost-effective and efficient review of new prescription drugs, biological products, and medical devices. We support reauthorization of these two important laws, which are scheduled to expire next year, and urge the earmarking of specific user fee funds for both pre- and post-market studies of prescription drugs, biological products, and medical devices.

2. Develop Public-Private Partnerships to Conduct Post-Marketing Studies of Drugs and Devices

An overwhelming majority of Americans have their health care financed through or administered by health insurance plans. As a result, health insurance plans have comprehensive data sets that could be used in evaluating safety and effectiveness. We recommend that FDA work with health plans and other key stakeholders to design post-marketing studies that will draw upon these de-identified data. We would be delighted to bring together representatives of health plans and FDA staff to discuss this issue.

The Centers for Medicare & Medicaid Services (CMS) also can provide important information about drug, biologic, and device usage for older Americans and for the disabled. These data, coupled with information available from health insurance plans, could provide an expanded view of how prescription drugs, biological products, and devices impact patient outcomes.

We recommend that FDA work with CMS to establish appropriate protocols to utilize Medicare data in the development of post-marketing studies. We are available to participate in this dialogue to ensure that data sets available from health insurance plans can be integrated into data available from CMS.

3. Provider Early Warning Monitoring Through Linkages to the National Health Information Infrastructure

Health plans have taken a leading role in using information technology to improve health quality and care outcomes through activities such as electronic prescribing, creation of personal health records, and development of decision support tools for consumers and caregivers. These initiatives are part of a larger effort by the health care community to create an electronic "health information highway" to link physicians, hospitals, health plans, state and federal governments, and consumers.

We recommend that FDA consider ways to monitor drug and device safety through linkages with public and private health data systems. Such linkages will provide the tools to obtain early indications of potential problems with prescription drugs, biologics, and medical devices that impact patient safety.

4. Establish Procedures to Track Implanted Medical Devices

FDA's Center for Devices and Radiological Health (CDRH) recently published a report (*Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program*) discussing its process for post-market surveillance of medical devices. One important issue raised in the report is the lack of complete documentation in health care records at the time devices are implanted which results in an inability to monitor device performance. Unlike prescription drugs, which have a National Drug Code identifier, there is no currently reliable system to track medical devices.

We recommend FDA work with health plans, health care providers, standards organizations, and other stakeholders to establish procedures to track medical devices. This process should include the development of unique identifiers for medical devices that can be used for health reporting purposes and in the claims and payment process (such as the UB 04, HCFA 1500, and HIPAA 837 claim forms). In

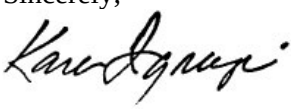
addition, a process should be developed to identify medical procedures that are performed as a result of device failures.

5. Encourage Accountability for Device Failures

Recent recalls of implantable defibrillators and pacemakers highlight the impact of device failures on patient safety and the cost of medical care. If device manufacturers are not held accountable for medical expenses associated with voluntary and involuntary device recalls, these costs are shifted to the public at large. We believe that manufacturers are responsible for all expenses related to a recall, including replacement costs, hospitalization, surgery, and other medical procedures to replace or repair the device. We recommend FDA use its existing authority to establish a process for medical device manufacturers to assume the cost of voluntary and involuntary device recalls. We have previously shared with FDA's General Counsel an analysis of this authority and would be happy to discuss this issue with you.

We believe the Food and Drug Administration plays an essential role in protecting patient safety and promoting quality health care for all Americans and we look forward to continuing our dialogue on how health plans can assist the FDA in this critical endeavor.

Sincerely,



Karen Ignagni